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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,939	11/14/2000	Conor Mulrooney	7146-106	1308

7590

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 09/11/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,939

Applicant(s)

MULROONEY, CONOR

Examiner

Suryaprabha Chunduru

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 11) filed on March 14, 2002 has been entered.
2. Claim 19 is canceled. New claims 21-24 are added. Thus claims 1-18, and 20-24 are pending in this office action and are considered for examination in this office action.

Response to Arguments

3. Applicant's response to the office action (Paper No.11) is fully considered and deemed persuasive.
4. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' amendment (Paper No.11).

New Grounds of Rejections

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- (i) Claims 1-18, 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 20 are indefinite in the recitation of the term 'possibly'. It is unclear whether any of the limitations, which follow the term possibly, are required limitations, i.e. is the 5' double stranded specific exonuclease activity optional or critical. Therefore, the metes and bounds of the claims are unclear.
- (ii) Claims 1-18, 20-24 are indefinite over the recitation of "capable of hybridizing" because capability is a latent characteristic and the claims do not set forth the criteria by which to

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determine capability. That is, it is not clear whether the recited probes have the potential to hybridize or do in fact do hybridize the to the recited target. Amendment of the claim to read, for example, "which hybridize" would obviate this rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 7-11, 13-18, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (EP 0 500 224 A2)('224) and in view of Walker et al. (USPN. 5,470,723) ('723).

Walker et al. ('224) teach a method for amplifying complementary first and second nucleic acid sequences each having a binding region at its 3' end wherein the method comprises (a) treating single stranded nucleic acid sequences with one or more primers (see column 10, lines 40-53) (in case of two primers, first primer hybridizes with first strand and the second

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primer hybridizes with the second strand (see column 7, lines 18-25); (c and d) in the presence of a double strand specific exonuclease (see column 10, lines 40-53) and (e) modified deoxynucleoside triphosphates (dNTPs), allowing the reaction to proceed for a period of time sufficient to generate amplified reaction products(see column 10, lines 46-57). Wlaker et al. ('224) also disclose that (a) the modified or substituted dNTPS incorporated during amplification are resistant to digestion (see column 8, lines 36-43); (b) exonuclease used was T7 gene 6 exonuclease (see column 11, lines 45-46, and column 8, lines 46-53); other exonucleases useful for the method include lamda exonuclease, klenow fragment of DNA polymerase I and Bst polymerase (see column 8, lines 51-53, and column 9 lines 1-6); the primer length could be 15-100 nucleotides (see column 8, lines 15-16). Though Walker et al. ('224) teach use of one or more primers, (disclosed use of two primers) Walker et al. ('224) did not specifically teach third and fourth primer.

Walker et al. ('723) teach a multiplex nucleic acid amplification method wherein Walker et al ('723) disclose use of four primers and amplification of multiple targets (see column 21, lines 40-63). Walker et al. ('723) also teach one member of a single pair of amplification primers are complementary to one of the two original target sequences and the other member of the pair is complementary to the other of the two original target sequences (see column 5, lines 55-62, column 11, lines 21-31) implying multiple primers used in the method are complementary to at least one of the members of a single pair of primers, and could also be used for nested PCR reaction.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of amplification of single stranded nucleic acid

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sequences as taught by Walker et al. ('224) with the method of multiplex amplification as taught by Walker et al. ('723) which is well known in the art at the time the invention was made, because Walker et al. ('224) states that "the instant method is readily applicable to the generation of multiple copies of a single strand nucleic acid sequence" (see column 10, lines 10-13). An ordinary practitioner would have been motivated to combine the method of ('224) with the method of ('723) in order to achieve the expected advantage of a rapid and sensitive method for detecting a multiple target sequences.


Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
August 29, 2002


JEFFREY FREDMAN
PRIMARY EXAMINER